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December 21, 1999

*Northwest Center  
for Infertility and Reproductive  
Endocrinology*

*Wayne S. Maxson, M.D.\**

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*Subspecialty Certified  
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Dockets Management Branch  
(HFA-350)  
Food and Drug Administration  
5360 Fishers Lane, RM 1061  
Rockville, MD 20852

RE: Docket #97N484S, Suitability Determination for donors of human,  
cellular, and tissue-based products

Dear Sir or Madam:

This letter is written in strong objection to the proposed rules for oocyte donors. As you know, the current practice of oocyte donation has evolved to a very effective method for establishing pregnancies in many deserving couples. This process is expensive and almost universally not covered by insurance. The availability of suitable and willing donors is also somewhat limited. To my knowledge, there has not been a single reported instance of viral transmission from an oocyte donor to a recipient. In addition, there appears to be no clear-cut evidence of the ability of an egg to transfer a virus and infect a recipient in any event.

While we certainly agree with the need for caution in transferring human substances and tissues between individuals, the proposed rules will significantly increase embryo loss, cost, inconvenience, and risk to the donor by decreasing pregnancy rates and making the whole process much more onerous. Cryopreservation of embryos will significantly increase the cost of a donor embryo transfer. This will also decrease the number of viable embryos available and increase the possibility of embryo misplacement, destruction, or mistake in transfer. The majority of women receiving donor oocytes are of advancing age, most in their 40's. From both a health and social point of view, any further delays in conception are unconscionable and provide increased risk to both mother and baby.

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Since the potential risk for an oocyte-carrying disease remains hypothetical, it is entirely inappropriate to completely change a system that is working and providing a good service to our patients.

Our Program is vehemently opposed to the proposed rules which would require cryopreservation and quarantine embryos resulting from donor oocytes. We routinely check all oocyte donors for HIV, RPR, hepatitis C antibody and hepatitis B antigen, as well as for gonorrhea and Chlamydia.

Please feel free to contact us if you have any questions which we can answer. Best regards,

Sincerely,

A handwritten signature in dark ink, appearing to read "Wayne S. Maxson", with a stylized flourish at the end.

Wayne S. Maxson, M.D.

David I. Hoffman, M.D.

Steven J. Ory, M.D.

Marcelo J. Barrionuevo, M.D.

WSM/sb

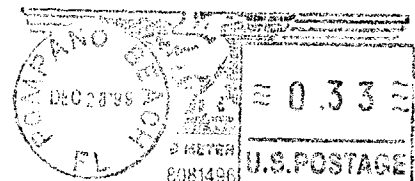
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